



JAN 08 2004

FORM PTO-1449

**LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENT**

ATTY. DOCKET NO.	SERIAL NO.
559P019	09/895,463
A.K. Gunnar Aberg	
FILING DATE	GROUP
June 29, 2001	2122 1614

**REFERENCE DESIGNATION****U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA	5,236,956	8/1993	Sjogren et al.	514	617	
AB	5,382,600	1/1995	Jonsson et al.	514	603	
AC	5,532,278	7/1996	Aberg et al.	514	617	
AD	5,559,269	9/1996	Johansson et al.	564	443	
AE	5,677,346	10/1997	Aberg et al.	51	617	
AF	5,686,464	11/1997	Johansson et al.	514	315	
AG	5,736,577	4/1998	Aberg et al.	514	617	
AH	5,922,914	7/1999	Gage et al.	564	413	
AI						
AJ						

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	YES	NO
						YES	NO	
BA	0 325 571	7/1989	Europe					
BB	0 667 852	8/1995	Europe					

**OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)**

(1) Nilvebrant et al.: Tolterodine - a new bladder-selective antimuscarinic agent. *Europ. J. Pharmacol.* 1997, 327: 196-207

--- There are over 20,000 publications on the drug tolterodine. This publication by Nilvebrant et al. is one of the more comprehensive reviews of the pharmacological activities of tolterodine, written by the people that invented tolterodine.

CA

CB

CC

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(2) Nilvebrant et al.: Antimuscarinic potency and bladder selectivity of PNU-200577, a major metabolite of tolterodine. *Pharmacol Toxicol*, 1997, 81:169-172  
--- Describes 5-hydroxymethyl-tolterodine as a major metabolite of tolterodine

(3) Brynne et al.: Pharmacokinetics and pharmacodynamics of tolterodine in man: a new drug for the treatment of urinary bladder overactivity. *Int J Clin Pharmacol Ther* 1997, 35: 287-295  
--- Demonstrates that tolterodine undergoes extensive and variable hepatic first-pass metabolism. Both N-dealkylation and oxidation of the 5-methyl group are mentioned (see page 293, Discussion)

(4) Andersson et al.: Biotransformation of tolterodine, a new muscarinic antagonist, in mice, rats, and dogs. *Drug Metab Dispos*. 1998, 26:528-535  
--- The in vivo metabolism of tolterodine in mice, rats and dogs is described. Both dealkylated and 5-HM-oxidized metabolites are described

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4/10/04

*M* CE  
 (5) Gillberg, P-G, Sundquist, S.: Pharmacological profile of DDO1 and desethyloxybutynin (DEOB). J. Urol 1997, 157: 81 p (Abstract)

--- This publication concerns the antimuscarinic activity of the tolterodine metabolite 5-hydroxymethyl-tolterodine (here called DDO1) and an active metabolite of the competing drug oxybutynin (desethyl-oxybutynin, here called DEOB)

*CF* (6) Pharmacia-Upjohn: Prescribing Information for Detrol (tolterodine tablets)  
<http://www.detrol.com.pi/index.htm>

--- This is the official drug product information from the manufacturer. The metabolism of tolterodine is described on pages 1 and 2. On page 6 there is a discussion of the risk for QT prolongation. A prolongation of 10 - 20% in the dog is called a "slight prolongation" although it is well known that a prolongation of 25 - 30% is fatal.

*CG* (7) Postlind et al.: Tolterodine, a new muscarinic receptor antagonist, is metabolized by cytochromes P450 2D6 and 3A in human liver microsomes. Drug Metab Dispos 1998, 26: 289-293.

--- This publication describes how the metabolites of tolterodine (by specific liver enzymes). Both the formation of 5-hydroxymethyl-tolterodine and the secondary amine metabolite are described in detail.

*CH* (8) Stahl et al.: Urodynamic and other effects Of Tolterodine... Neurourol Urodyn 1995, 14: 647-655

--- This publication deals with clinical pharmacological activities and is part of the core documentation for tolterodine,

EXAMINER	DATE CONSIDERED
<i>Dwayne C over</i>	
EXAMINER: Initial reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

\*=English Abstract

SR=Cited in Search Report